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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,426	05/08/2001	Florence Bordon-Pallier	146.1364	4261

7590 08/10/2004
Bierman Muserlian and Lucas
600 Third Avenue
New York, NY 10016

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,426

Applicant(s)

BORDON-PALLIER ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7, 10-14 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 5 and 10-14 is/are allowed.
- 6) ☒ Claim(s) 3, 4, 7 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Re: Bordon-Pallier *et al*
Priority Date: 10 November 1998

1. The amendment filed 5/20/2004 is acknowledged and entered into the record. Accordingly, claims 16,8-9, and 15-18 are canceled without prejudice or disclaimer, and claim 19 is newly added.
2. Claims 2-5,7,10-14, and 19 are pending.
3. Claims 2-5,7,10-14, and 19 are examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 7 and now newly added claim 19 under 35 USC 112,1st paragraph as lacking written description is maintained for the reasons of record. Applicant argues that the claim is drawn to a *"DNA sequence that varies by a single codon, either suppressed, inserted or substituted that encodes a polypeptide having the biological properties of SEQ ID No: 2."* Applicant further argues that one of skill in the art would readily understand the meaning of claim 7. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

In order for a specification to comply with the written description guidelines, the specification must provide to one of skill in the art with distinguishing attributes shared by broad genus of variants as now claimed. Neither the specification nor the claims provide any information with regard to common structural attributes which are shared by

Art Unit: 1642

the broad genus so as to distinguish the claimed DNA molecule from other DNA molecules claimed. Although the claim does recite some functional language (i.e. having the same biological function of hTFIIIA), the specification does not provide substantial information or any characterization of the actual biological function of hTFIIIA. Therefore, it is unclear as to the limitation of having "the same biological function as human transcription factor hTFIIIA" would have on the claim, because such activity has not been duly described in the specification. Furthermore, reliance on the general knowledge and level of skill in the art does not supplement the omitted written description because specific, not general, guidance is required. Therefore, since the specification and the claims fail to provide common attributes, characteristics, and actual functional language for the broad genus of DNA molecules claimed, SEQ ID No: 2 alone is insufficient to represent the broad genus of DNA molecules claims. Thus the rejection under 35 USC 112, 1st paragraph as lacking written description is maintained.

Claim Rejections Maintained - 35 USC § 102

6. The rejection of claims 3-4, 7, and now newly added claim 19 under 35 USC § 102(b) is maintained for the reasons of record. Applicant argues that the sequence taught by Fujiwara *et al* is not the same as that instantly claimed because of differences in sequence homology. Applicant further argues that the examiner has not provided specific technical reasons as to why the instant invention lack novelty over the prior art. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Art Unit: 1642

It is noted that claim 2 as currently amended recites a DNA sequence that comprises the hTFIIIA gene coding for human transcription factor hTFIIIA of SEQ ID No: 2. The claim as originally presented was interpreted as open and as containing any sequence of SEQ ID No: 2. Likewise, claims 3 and 4 as currently interpreted are drawn to DNA sequences that contain any sequence of SEQ ID No: 3 or 4, and therefore, is anticipated by Fujiwara *et al.* The word contain or containing is given a broad interpretation and is interpreted as being open language (i.e. any sequence that is found within a sequence reads on the term contain). Thus Fujiwara *et al* teaches a sequence which is contained within SEQ ID No: 3 or 4, for example, nucleic acids 120-480 of Fujiwara *et al* are contained within SEQ ID No: 3.

In addition, claim 7 is drawn to any nucleic acid sequence comprising a modification to one nucleotide. Because Fujiwara *et al* teaches a nucleic acid sequence which is 96.5% homologous to SEQ ID No: 3 and is 96.2% homologous to SEQ ID No: 4, it too comprises a nucleic acid which comprises one modification. Moreover, the amendment to the claims does not specifically limit the number of modifications within the nucleic acid to just one because of the “comprising” language.

With regard to newly rejected claim 19, the claim is drawn to a peptide analog of SEQ ID No: 2, wherein the analog has been modified by substitution, suppression, or addition of one amino acid. Again, Fujiwara *et al* teach a polypeptide that has been modified to include at least one amino acid modification. Because the claim is interpreted as being open as having a modification, this does not specifically limit the number of modifications to a single amino acid.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 3-4, 7, and now newly added claim 19 under 35 USC § 102(b) is maintained for the reasons of record. Applicant's arguments are substantially similar to those already presented and rebutted above (see paragraph 6). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record and previously argued. Thus the rejection of claims under 35 USC 102(b) are maintained.

With regard to newly rejected claim 19, the claim is drawn to a peptide analog of SEQ ID No: 2, wherein the analog has been modified by substitution, suppression, or addition of one amino acid. Arakawa *et al* teach a polypeptide that has been modified to include at least one amino acid modification. Because the claim is interpreted as being open as having a modification, this does not specifically limit the number of modifications to a single amino acid.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 5/20/2004.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. Claims 2,5, and 11-14 are free of the prior art. Claims 3-4,7 and 19 are rejected.³

Art Unit: 1642

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/831,426
Art Unit: 1642

Page 7

Christopher Yaen
Art Unit 1642
August 6, 2004

A handwritten signature in black ink, appearing to read "Gary Nickol". The signature is written in a cursive, flowing style with a large initial "G".

GARY NICKOL
PRIMARY EXAMINER